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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,600	01/10/2002	Frederic Triebel	TRIEBEL=2A	5099

7590 06/03/2005

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/041,600	TRIEBEL, FREDERIC	
	Examiner	Art Unit	
	Karen A. Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,7 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 2, 4-6 and 8 have been canceled. Claims 1, 3, 7 and 9 have been amended and are under consideration.

2. Sections of Title 35, U.S. Code not found in this action can be found in a prior action.

3. The rejection of claims 1 and 3 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .

Claims 1 and 3 are drawn to composition comprising tumor cells transfected with a "derivative" of CD4 or LAG-3. The specification states on page 5, lines 1-2 that "derivatives" of LAG-3 are mutants and varaints of LAG-3 which maintain the ability to bind to the ligand of LAG-3. The specification exemplifies mutant forms of LAG-3 starting on page 5, line 17, but the exemplifications provided are not limiting. The specification defines a CD4 derivative on page 6, lines 7-9 as able to bind the MHC class II ligand of CD4 and which inlcudes variant and mutants. Thus the claims encompass a genus of LAG-3 derivative and a genus of CD-4 derivatives which comprise molecules which are able to bind to the MHC class II ligands of LAG-3 and CD4. Both genuses are highly varaint because they tolerate members which differ significantly in strucutre from LAG-3 and CD4 and require only the conservation of ligand binding activity. Further "mutants" are recognized in the art to be the result of a random event. Therefore there is no nexus between the sequence of LAG-3 and CD4 and their respective mutants. One of skill in the art would not be able to anticipate the structre of a LAG-3 or CD4 "mutant". reasonable conlcude that applicant was not in possession the claimed genus of derivatives, cells expressing said derivatives and method of making said cells.

4. Claims 1, 3, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Weiner et al (WO 94/16737).

Claim 1 is drawn to tumor cells transfected with a DNA encoding at least one MHC class II ligand selected from the group constiting of CD4, LAG-3 and derivatives thereof. Claim 3 is drawn to the process of preparing the tumor cell of claim 1 comprising removing tumor cells from a pateint and transfected said tumro cells with the DNA encoding for LAG-3 or CD4.

Claim 7 is drawn to a pharmaceutical composition for treating a pathological conidtion comprising cells transfected with, and expressing, the DNA encoding LAG-3 or CD4, and a pahrmaceutically acceptible carrier. Claim 9 is drawn to a method of treating a pathological condition involving antigne-specific T-cell mediate immune response, comprising administering the pharmacetuical comprising of claim 7 to a subject in need thereof.

Weiner et al disclose a method for making a tumor cell transfected with, and expressing, CD4 (page 52, lines 10-15 and page 56, lines 2-5). Wiener et al disclose a method of treating cancer in a subject in need thereof by the administration of said cell in a pharmaceutically acceptible carrier (page 56, lines 23-26).

5. Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Huard et al (PNAS, May 1997, Vol. 94, pp. 5744-5749).

Huard et al disclsoe a composition comprising COS cells transfected with and expressing wild-type LAG-3, and cells expressing mutatns of LAG-3 (page 5745, first column, lines 13-20). It is noted that the intended use of a product does not impart patentable wieght to a claim.

6. Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by the abstract of Baron et al (Eur J Immunol. 1994 Aug;24(8):1933-6) .

The specific embodiemtn of claim 7 is recited above.

The abstract of Baron et al discloses a pharmacetuical composition comprising CD4-CD8+ T cells from beta 2-microglobulin-deficient mice transefected with and expressing CD+4. Claims 7 is also included in this rejection because the recitation of an intended use does not confer patenable wieght on the claimed product.

7. All other rejections and objections are withdrawn in light of applicants amendments and terminal disclaimer

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
5/31/2005

KAREN A. CANELLA PH
PRIMARY EXAMINER